

One Step Test For HbA1c (Colloidal Gold)**For In Vitro Diagnostic Use**

Cat.# CG1017

User Manual**INTENDED USE**

One Step Test for HbA1c is intended for the quantitative measurement of HbA1c in whole blood. This test is used as an aid for monitoring glycemic control in diabetics. In addition, it can identify people at risk of developing the disease and ongoing monitoring.

SUMMARY

Hemoglobin is the protein molecule in red blood cells with the main function transport oxygen and carbon dioxide in blood. HbA1c belongs to the glycated hemoglobins, a fraction formed by the attachment of various sugars to the Hb molecule and is proportional to average blood glucose concentration over the previous four weeks to three months. One advantage of using HbA1c for diagnosis is that the test does not require a fasting blood sample. Although HbA1c testing is mainly used for monitoring blood sugar control in patients with diabetes, the World Health Organization (WHO) now recommends that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values.

PRINCIPLE

The test uses an anti-human Hb monoclonal antibody conjugated with colloidal gold and an anti-human HbA1c monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human Hb monoclonal antibody binds with the HbA1c and Hb in sample proportionally and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The color intensity of the test line increases in proportion to the amount of HbA1c in sample.

Then insert test card into the FIA8000 Quantitative Immunoassay Analyzer (hereafter referred to as FIA8000), the concentration of HbA1c is measured and displayed on the screen. The HbA1c concentration is stored in the FIA8000 and is available on demand. The result can be transmitted to the lab or hospital information system, if it is connected to FIA8000.

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A kit contains:

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5. Sample diluent	25

A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (the colloidal gold is coated with gold-labelled anti-human HbA1c monoclonal antibody, the test line is coated with an anti-human HbA1c polyclonal antibody, and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Sample diluent:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.

Use the test card within 1 hour once the foil bag is opened.

Store the sample diluent at 0~30°C with a valid period of 24 months.

Store the sample diluent at 2~8°C for better results.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.

3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not open pouches until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for whole blood samples. Heparin, sodium citrate and EDTA can be used as the anticoagulant under aseptic conditions.
2. The test is for human blood, other specimens or bodily fluids may not get accurate results.
3. The test should be performed within 4 hours after whole blood collection.
4. Samples could be kept for 7 days at 2~8°C and avoid cryopreservation.
5. Samples must be recovered to room temperature before testing.
6. SAMPLE VOLUME: 10 µl

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in accordance with test kit lot No. Perform "QC (SD)" calibration when necessary (Details refer to 8.2.1 of FIA8000 User Manual).
4. On the main interface of FIA8000, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver 10 µl of sample into one tube of sample diluent, mix gently and thoroughly. Then drop 120 µl of sample mixture (or 3~4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. Reaction time: 3 minutes. Insert the test card into FIA8000 and press "ENT" button after reaction time is elapsed. The test card can be detected and the result will be printed automatically.

Notes:

1. It is required to perform "SD Card Calib" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Valid: When a purplish-red band appears at the control area(C), use FIA8000 to analyze the test card and get the result.

Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

EXPECTED RANGE OF VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.8%-5.8%.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2%-14%
Lower Detection Limit	≤2%
Within-Run Precision (n=10)	≤5%
Between-Run Precision	≤8%

Accuracy: verify with comparison experiments, the correlation coefficient $r \geq 0.990$, the relative error $\leq 20\%$.

LIMITATIONS

1. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of them is as follows:

Interferent	Concentration (Max)
Triglyceride	25g/L
Bilirubin	0.1g/L

REFERENCES

- Cagliero E, Levina E V, Nathan D M. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients[J]. Diabetes care, 1999, 22(11): 1785-1789.
- Özdamar Ö, Gün İ, Keskin U, et al. The role of maternal serum beta-HCG and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia[J]. 2014.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HbA1c Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration Date
	Do not reuse		Date of manufacture
	Consult instructions for use		Batch code
	Temperature limitation		<i>In vitro</i> diagnostic medical device
	Sufficient for		Authorized representative in the European Community
	CE mark		

Thank you for purchasing HbA1c Fast Test Kit (Colloidal Gold).

Please read this user manual carefully before operating to ensure proper use.

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